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# Overruling the Food and Drug Administration:

## An Analysis of the 2011 Denial of Over-the-Counter Status for Plan B Placed within the Historical Context of Executive Influence on FDA Action

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## Abstract

*On December 7, 2011, newspaper headlines from coast to coast announced that Plan B One-Step, a form of emergency contraception, would not be made available to females under seventeen without a prescription. The denial of over-the-counter (“OTC”) status, though newsworthy itself, drew particular attention because of the unusual nature of the decision. As the New York Times announced, “[f]or the first time ever, the Health and Human Services secretary publicly overruled the Food and Drug Administration . . . no health secretary had ever publicly done so . . . .”<sup>1</sup> This paper analyzes the novel and much-discussed public overruling of the Food and Drug Administration Commissioner by the Secretary of Health and Human Services (“HHS”) regarding the prescription-only status of Plan B One-Step for women under seventeen.*

*Part I begins by briefly detailing the history of emergency contraception from its creation through the new drug application process, court battles, and repeated efforts to obtain OTC status for Plan B. In Part II, I move forward in time to the most recent 2011 supplemental new drug application for Plan B and the subsequent December 7 decision, exploring in detail the declared reasoning of the FDA and HHS, the evidence presented, and the practical consequences of the decision for adolescent females. In Part III, I endeavor to place the overruling of the FDA in historical and legal context. Looking to the statements of former FDA employees, I explore reports of previous assertions of HHS authority over the FDA dating back to the 1950’s, and I review the legal source of that authority. Finally, I conclude by suggesting that the December 7 Plan-B decision, though unique in its public nature, was in fact consistent with a long history of behind-the-scenes HHS influence on FDA decisions. I also argue that the December 7 decision can be viewed as step towards more transparent agency decision making.*

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<sup>1</sup> Gardiner Harris, *F.D.A. Overruled On Availability Of After-Sex Pill*, N.Y. TIMES, Dec. 8, 2011 at A1.

## Introduction

Emergency contraception, for more than a decade now, has sparked intense interest in the scientific, political and religious communities, touching as it does on a broad array of topics ranging from abortion to sexual health to parental control and more. To its detractors, the so-called “morning-after pill” is a moral hazard, a dangerous abortifacient, and a threat to the welfare of American families that ought to be restricted to prescription status if not banned.<sup>2</sup> To its advocates, the drug is an extension of the traditional birth control pill that offers the promise of female autonomy and the safe prevention of unplanned pregnancies<sup>3</sup> such that it ought to be stocked on drug store shelves alongside condoms and pregnancy tests.<sup>4</sup>

For the purposes of this paper, Plan B One-Step (“Plan B”) is defined functionally; Plan B is a type of emergency contraception<sup>5</sup> taken orally that contains 1.5 mg of levonorgestrel and, when taken within three days of unprotected intercourse, prevents pregnancy in roughly seven out of eight women who would otherwise have gotten pregnant.<sup>6</sup> It is still contested whether Plan B functions solely by preventing ovulation or whether it could also prevent implantation of a fertilized egg, though “the weight of evidence suggests that [emergency contraceptive] drugs

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<sup>2</sup> Deirdre McQuade of the U.S. Conference of Catholic Bishops asserted that Plan B “could endanger the lives of newly conceived children through its abortifacient action, put minors at risk for unnecessary side effects, undermine parental rights and contribute to higher STD rates.” Rob Stein, *Wider access to Plan B is rejected*, WASH. POST, Dec. 8, 2011, at A01.

<sup>3</sup> “Emergency contraception is a safe and effective way to prevent pregnancy after unprotected intercourse. . . The morning-after pill is not the abortion pill. Emergency contraception is birth control, not abortion.” *Morning-After Pill (Emergency Contraception)*, PLANNED PARENTHOOD, <http://www.plannedparenthood.org/health-topics/emergency-contraception-morning-after-pill-4363.asp>.

<sup>4</sup> Kirsten Moore of Reproductive Health Technologies Project expressed hope that Plan B “will be right on the shelves between the condoms and the pregnancy tests,” arguing that OTC status for Plan B is “good news for women’s health and long overdue.” Rob Stein, *FDA Considers Putting Plan B in Drugstore Aisles*, WASH. POST, Dec. 6, 2011, at A12.

<sup>5</sup> I refer to Plan B as a type of emergency contraception rather than an abortifacient consistent with both FDA policy and with the definition of pregnancy promulgated by the American College of Obstetricians and Gynecologists. Because Plan B, like traditional birth control pills, does not affect an implanted, fertilized egg, it is properly classified as a form of contraception. For more information on the distinction between abortifacients and contraceptives, see Renee C. Wyser-Pratte, *Protection of RU-486 as Contraception, Emergency Contraception, and as an Abortifacient under the Law of Contraception*, 79 Or. L. Rev. 1121 (2000).

<sup>6</sup> Teva’s Women’s Health, Inc., *What Plan B One-Step Is*, PLAN B ONE-STEP, <http://planbonestep.com/description-plan-b.aspx> (last visited May 5, 2012).

never work by preventing implantation.”<sup>7</sup> Although Plan B is not the only form of emergency contraception,<sup>8</sup> it is the focus of this paper.

On December 7, 2011, Plan B made national headlines when Commissioner Margaret Hamburg of the Food and Drug Administration (“FDA”) announced that “adequate and reasonable, well-supported, and science-based evidence [shows] that Plan B One-Step is safe and effective and should be approved for nonprescription use for all females of child-bearing potential.”<sup>9</sup> For a moment, it seemed as though emergency contraception proponents had prevailed and Plan B would soon be available to all as an OTC drug. However, the Commissioner then made a remarkable announcement; Secretary of Health and Human Services (“HHS”) Kathleen Sebelius, invoking her authority under the Federal Food, Drug, and Cosmetic Act, had directed the Commissioner of the FDA not to grant OTC status to Plan B for females under the age of seventeen.<sup>10</sup>

The December 7 decision exposed – in a very public fashion – the typically behind-the-scenes involvement of HHS in FDA decisions, attracting criticism from those who argued that the Obama administration improperly allowed politics to triumph over science.<sup>11</sup> In the subsequent months, law suits,<sup>12</sup> letters from Congressmen,<sup>13</sup> and numerous newspaper articles<sup>14</sup>

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<sup>7</sup> Valerie B. Satkoske, Lisa S. Parker, *Emergency Contraception Policy: How Moral Commitments Affect Risk Evaluation*, 9 LAW, PROBABILITY & RISK 187, 190 (2010).

<sup>8</sup> For example, certain intrauterine devices like the Copper-T IUD offer even greater odds of preventing pregnancy when inserted shortly after unprotected intercourse. See Judy Mann, *A Birth Control Option Worthy of Mention*, WASH. POST, Dec. 19, 1997, at E3; see also Kelly Cleland et al., *The Efficacy Of IUDs For Emergency Contraception: A Systematic Review Of 35 Years Of Experience*, HUM. REPROD., May 8, 2012 at 1–7. doi:10.1093/humrep/des140 available at <http://humrep.oxfordjournals.org/citmgr?gca=humrep;des140v1>.

<sup>9</sup> Statement from FDA Commissioner Margaret Hamburg on Plan B One-Step, FDA (Dec. 7, 2011), available at <http://www.fda.gov/NewsEvents/Newsroom/ucm282805.html> [hereinafter Hamburg Statement].

<sup>10</sup> *Id.*

<sup>11</sup> Editorial, *Politics and the Morning-After Pill*, N.Y. TIMES, Dec. 8, 2011, at A38 (“Once again, the politics of birth control have trumped science and sound public policy.”).

<sup>12</sup> The Center for Reproductive Rights has filed suit in federal district court, arguing that the FDA’s and Sebelius’s decision to deny OTC status to Plan B for women under seventeen was invalid. See Rob Stein, *Judge Rejects Plan B Challenge, May Review FDA Decision*, WASH. POST, Dec. 14, 2011, at A02; see also Associated Press, *Morning-After Pill Can Get A Hearing*, BOSTON GLOBE, Dec. 14, 2011 at 8.

have attacked the actions of the Secretary of HHS (“Secretary”), the president, and the FDA. Papers from coast to coast heralded the action as unprecedented, proclaiming it the first time the Secretary had publicly overruled the Commissioner of the FDA (“Commissioner”).<sup>15</sup> As a result, many were left wondering if Sebelius’s decision and the subsequent FDA action were lawful and, to the extent political concerns governed Sebelius’s actions, whether such considerations were appropriate.

Before one can analyze the appropriateness and historical significance of the December 7 decision, however, it is absolutely essential to place the Plan B decision in context. Accordingly, this paper begins with a brief overview of the history of Plan B from creation to FDA approval, through court cases and multiple requests for OTC status. In Part II, I analyze the most recent petition for OTC status, explaining the review process to which Plan B was subjected, the study results presented, and the rationales for Hamburg’s and Sebelius’s decisions. I also address the potential consequences of the decision for adolescent females. Then, in Part III, I look closely at the relationship between HHS and the FDA, analyzing the legal authority upon which Sebelius relied as well as the historical role HHS has played in influencing FDA decisions both in and out of the public eye. In this section, I examine interviews with FDA employees and former Commissioners dating back to the 1960’s which collectively reveal countless instances of behind-the-scenes political influences on FDA decisions.

Ultimately, I conclude by observing that HHS in fact has a long history of exerting influence over FDA Commissioners and regulations, that the December 7 decision was unique

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<sup>13</sup> “Fourteen Democratic members of Congress wrote a letter asking Sebelius to substantiate the scientific basis of her decision.” Jill U. Adams, *The Push-Pull Over Morning-After Pill; Obama Administration Keeps Access Restricted*, L.A. TIMES, Dec. 19, 2011, at E1.

<sup>14</sup> See, e.g., Editorial, *Wrong Call On Plan B*, WASH. POST, Dec. 11, 2011, at A1; see also Editorial, *Politics and the Morning-After Pill*, N.Y. TIMES, Dec. 8, 2011, at A38.

<sup>15</sup> See, e.g., Harris, *supra* note 1, at A1 (“For the first time ever, the Health and Human Services secretary publicly overruled the Food and Drug Administration . . . no health secretary had ever publicly done so . . .”).

only in so far as it was public, and that regardless of whether political considerations ought to play a role in the regulation of food and drugs, they have in fact done so intermittently for the past fifty years. Moreover, Sebelius's overruling of the FDA could in fact be considered a step towards greater transparency in agency decision making, as it moved what has traditionally been a decision made behind closed doors to the forefront of public attention.

## **I. The Emergence of Emergency Contraception and the Development of Plan B**

In the 1990's, more than thirty years after first approving the use of daily oral contraceptives, the FDA began tackling the issue of emergency contraception. Although the FDA in 1994 denied a citizen petition to require labeling for the use of oral contraceptives as emergency contraception,<sup>16</sup> by 1997, the FDA acknowledged that emergency contraception "substantially reduces the chances of becoming pregnant after unprotected sexual intercourse," and the agency began actively soliciting emergency contraception supplemental new drug applications ("NDAs") from oral contraception manufacturers.<sup>17</sup> The FDA Deputy Commissioner at the time, Mary Pendergast, publicly announced that the FDA was "trying to pave the way for greater access to emergency contraception,"<sup>18</sup> likely in an effort to encourage drug manufactures who feared the sale of emergency contraception would lead to consumer boycotts by those who equated emergency contraception with abortion.<sup>19</sup>

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<sup>16</sup> Michele Slachetka, *Getting To Plan B: A History Of Contraceptive Rights In The United States And An Argument For A Private Right Of Action Against The Fda*, 16 WM. & MARY BILL RTS. J. 345, 350 (2007) (describing the 1994 citizen petition filed by the Center for Reproductive Law and Policy).

<sup>17</sup> *Id.* at 351; see also *FDA Calls for Applications for Emergency Use of Oral Contraceptives*, 27 FDA MED. BULL. 27, no. 1 (March 1997).

<sup>18</sup> Tamar Lewin, *U.S. Agency Wants the Pill Redefined*, N.Y. TIMES, July 1, 1996, at A1.

<sup>19</sup> For a discussion of the political and legal climate of the time and its effects on oral contraception manufactures, see Marian Lee, *When Plan A Fails, We Need Plan B: Over-the-Counter Access to Emergency Contraceptive Pills* (2004), in *FOOD AND DRUG LAW: AN ELECTRONIC BOOK OF STUDENT PAPERS* (Peter Barton Hutt, ed.) (citing Peter Keating, *Where Drug Firms Fear to Tread*, FORTUNE, Oct. 26, 1998, at 48).

By September 1998, the FDA's solicitation of supplemental NDAs paid off and the first emergency contraception kit – Preven – was approved.<sup>20</sup> Ten months later, in July of 1999, the FDA approved the original two-pill version of Plan B for use as emergency contraception by prescription.<sup>21</sup> The initial version of Plan B, later replaced by Plan B One-Step, required women to take two levonorgestrel tablets twelve hours apart and was produced by Women's Capital Corporation ("Women's Capital"). Both the original version of Plan B and its current One-Step formula have the same time constraints; in order to be effective, the drug should be taken within seventy-two hours of intercourse, and the earlier it is taken within that time frame, the more effective it is in preventing pregnancy.<sup>22</sup> Specifically, the drug is 95 percent effective at preventing pregnancy when it is taken within twenty-four hours of having unprotected intercourse.<sup>23</sup>

In April 2003, Women's Capital filed a supplemental NDA in an effort to switch Plan B from prescription to OTC status. In support of the switch, Women's Capital submitted Plan B's actual use study data, which revealed that "the frequency of unprotected sex did not increase, condom use did not decrease, and the overall use of effective contraception did not decrease."<sup>24</sup> The medical community, as represented by the American Medical Association, the World Health Organization and others, strongly supported the prescription-to-OTC switch.<sup>25</sup> Moreover, the FDA's own Joint Advisory Committee – comprised of the Nonprescription Drug and

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<sup>20</sup> Kathleen Doheny, *Emergency Contraceptive Opens New Era*, L.A. TIMES, Sept. 14, 1998, at S6.

<sup>21</sup> Slachetka, *supra* note 16, at 351; Lee, *supra* note 19, at 20.

<sup>22</sup> See Tummino v. Torti, 603 F. Supp. 2d 519, 522 (E.D.N.Y. 2009); *see also* Teva Pharmaceuticals, Inc., *Frequently Asked Questions*, PLAN B ONE-STEP, <http://planbonestep.com/plan-b-faq.aspx>.

<sup>23</sup> *The Difference between Emergency Contraception (The Morning After Pill) and Medication Abortion*, PLANNED PARENTHOOD, <http://www.plannedparenthood.org/mar-monte/the-difference-between-ec-and-medication-.htm> (last visited April 15, 2007).

<sup>24</sup> Tummino, 603 F. Supp. 2d at 528.

<sup>25</sup> See Natasha Singer, *Contraception Pill Strictures Are Eased by a Judge*, N.Y. TIMES, Mar. 24, 2009, at A12 ("In 2001 more than five dozen public health groups, with endorsements from World Health Organization and the American Medical Association, asked the F.D.A. to make Plan B available over the counter.")



Reproductive Health Drugs Advisory Committees – voted in favor of the switch by a margin of twenty-three to four in December of 2003,<sup>26</sup> concluding that the drug was “extraordinarily safe,” and that it was the “safest produc[t] before the panel in four years.”<sup>27</sup> Despite the positive safety assessment of Plan B and the FDA’s history of following its advisory committees’ recommendations,<sup>28</sup> the FDA chose to delay its decision on the switch, exceeding the standard ten-month timetable for decision mandated by the Prescription User Drug Free Act.<sup>29</sup>

Meanwhile, Barr Laboratories (“Barr”) acquired Women’s Capital,<sup>30</sup> and the company submitted a newly amended application in July 2004, this time seeking to make Plan B an OTC drug for females sixteen-years-old and older.<sup>31</sup> The FDA, however, rejected the amended application and the request for an OTC switch in May 2004, citing insufficient data on safety for use by females under sixteen without physician supervision.<sup>32</sup> Significantly, “Dr. McClellan, the Acting Deputy Commissioner, did not make the decision on his own. The White House had made it clear to him that an OTC Plan B would be politically unpopular and that the public ‘needed to have the message that we were taking adolescents and reproductive issues seriously.’”<sup>33</sup>

This May 2004 decision prompted forty-eight members of congress to request a report on the FDA’s decision-making process, and the report released by the Government Accountability Office (“GAO”) concluded that process of considering Plan B for OTC status was “unusual,”

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<sup>26</sup> Tummino, 603 F. Supp. 2d at 528.

<sup>27</sup> *Id.* (quoted in Vanessa Lu, *The Plan B Age Restriction Violates A Minor's Right To Access Contraceptives*, 44 FAM. L.Q. 391, 403 (2010)).

<sup>28</sup> Gina Kolata, *A Contraceptive Clears a Hurdle to Wider Access*, N.Y. TIMES, Dec. 17, 2003, at A1.

<sup>29</sup> Marc Kaufman, *FDA Delays Decision on ‘Morning After Pill’*, WASH. POST, Feb 14, 2004, at A15.

<sup>30</sup> Leila Abboud, *Barr Buys Maker Of Contraceptive For Morning After*, WALL ST. J., Oct. 3, 2003, at B1.

<sup>31</sup> See Letter from Randall W. Lutter, Associate Commissioner for Policy and Planning, FDA, to Bonnie Scott Jones, Esq., Center for Reproductive Rights (June 9, 2006), available at [http://www.fda.gov/ohrms/dockets/dockets/01p0075/01p-0075-pdn001-vol348.pdf?utm\\_campaign=Google2&utm\\_source=fdaSearch&utm\\_medium=website&utm\\_term=Plan%20B%20citizen%20petition&utm\\_content=1](http://www.fda.gov/ohrms/dockets/dockets/01p0075/01p-0075-pdn001-vol348.pdf?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=Plan%20B%20citizen%20petition&utm_content=1), at 2.

<sup>32</sup> *Id.*

<sup>33</sup> Tummino, 603 F. Supp. 2d at 529.

primarily due to: 1) the disagreement of the Directors of the Office of Drug Evaluation, 2) the atypical involvement of FDA leadership, 3) the suggestion that the decision was made before the application had been reviewed, and 4) the novel reliance upon behavioral factors regarding teenage sexual activity to determine the outcome when such factors were not normally considered for an OTC switch.<sup>34</sup> Also of note to the GAO was the fact that prior to Plan B, there were “no age-related marketing restrictions for safety reasons for any of the prescription or OTC contraceptives that FDA has approved.”<sup>35</sup>

While the GAO investigated, Barr submitted yet another application in July 2004, this time addressing the FDA’s concern about simultaneously producing a drug that would require both prescription and OTC labeling. Once again, the FDA exceeded the allotted time for review – to great congressional ire<sup>36</sup> – and further delayed decision making by requiring an additional sixty days for public comment. This culminated in an August 2005 announcement that the FDA faced an indefinite delay regarding Plan B due to logistical concerns about labeling and selling a drug simultaneously as both a prescription and OTC product to women based on differing ages.<sup>37</sup> Of particular concern was how pharmacists would be able to distinguish between age groups that could obtain the drug only by prescription and those that could purchase it OTC.

In the wake of this final delay, several FDA officials resigned in protest.<sup>38</sup> On August 18, 2006, Barr once more submitted an application for OTC status, this time arguing for OTC

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<sup>34</sup> U.S. GOV’T ACCOUNTABILITY OFFICE, FOOD AND DRUG ADMINISTRATION: DECISION PROCESS TO DENY INITIAL OVER-THE-COUNTER MARKETING OF THE EMERGENCY CONTRACEPTIVE DRUG PLAN B WAS UNUSUAL (2005), at 19.

<sup>35</sup> *Id.* at 6.

<sup>36</sup> The Senate expressed its disapproval of the FDA’s delay on Plan B at FDA Commissioner confirmation hearings, requiring promises of prompt action before it would allow confirmation. *See, e.g., Nomination of Andrew von Eschenbach and Paul DeCamp: Hearing Before the S. Comm. on Health, Educ., Labor, & Pensions*, 109th Cong. (2006).

<sup>37</sup> Tummino, 603 F. Supp. 2d at 523.

<sup>38</sup> *See, e.g., Marc Kaufman, FDA Official Quits Over Delay on Plan B*, WASH. POST, Sept. 1, 2005, at A08.

availability only for consumers eighteen and older.<sup>39</sup> The FDA, on August 24, 2006, approved Barr's application, allowing for OTC availability of Plan B for users eighteen years of age and older.<sup>40</sup> Two years later, in 2008, Teva Pharmaceutical Industries ("Teva") purchased Barr and acquired control over the manufacture and sale of Plan B.<sup>41</sup>

Finally, in March 2009, a lawsuit filed by the Center for Reproductive Rights challenging the FDA's failure to grant OTC status to Plan B for those under eighteen finally concluded in March 2009. Discovery related to the lawsuit had made public the fact that the "political sensitivity" of the switch was explicitly discussed by Deputy Commissioner Lester Crawford and the FDA review staff, that Commissioner Mark McClellan had spoken with the Deputy Assistant to the President for Domestic Policy about the switch,<sup>42</sup> and that Dr. Janet Woodcock, director of CDER, said that "a denial was necessary 'to appease the [present] administration's constituents.'"<sup>43</sup> These factors, taken together, incensed Judge Korman, who openly expressed his disapproval of the politicization of the Plan B decision.

In his opinion, Judge Korman ruled against the FDA, holding that Plan B had to be made available to seventeen-year-olds OTC and remanding the Center for Reproductive Rights' citizen petition to the FDA so that the agency could reconsider OTC availability of Plan B for younger females.<sup>44</sup> Additionally, Judge Korman took the unusual step of finding that the FDA had "acted in bad faith and in response to political pressure" and that its age restriction determination

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<sup>39</sup> Tummino, 603 F. Supp. 2d at 536.

<sup>40</sup> *Id.*

<sup>41</sup> Shirley S Wang, *Teva To Buy Us Generic Rival Barr For \$7.46 Billion*, WALL ST. J., July 19, 2008 at B5.

<sup>42</sup> Robert V. Percival, *Who's In Charge? Does The President Have Directive Authority Over Agency Regulatory Decisions?*, 79 FORDHAM L. REV. 2487, 2521-24 (2011) (citing Tummino v. Torti, 603 F. Supp. 2d 519, 527 (E.D.N.Y. 2009)).

<sup>43</sup> *Id.* (citing Tummino, 603 F. Supp. 2d at 530).

<sup>44</sup> Tummino, 603 F. Supp. 2d at 550.

“lacks all credibility.”<sup>45</sup> The next month, in April 2009, the FDA announced that it would not appeal the *Tummino* decision and that Plan B could be sold OTC to those seventeen and older.<sup>46</sup> Three months later, the FDA approved the current form of Plan B – Plan B One-Step – on July 13, 2009.<sup>47</sup>

## II. Teva’s 2011 Application for Unrestricted OTC Availability of Plan B

After three failed attempts to obtain OTC status for Plan B that extended to minor users, Teva decided to try its luck with a fourth effort in February 2011 and submitted a supplemental NDA “requesting full nonprescription status for Plan B One-Step without an age restriction.”<sup>48</sup> Having learned from previous efforts and armed with new data, including a study of 335 girls between the ages of twelve and seventeen, Teva presented evidence that “between 72 percent and 96 percent of them understood the proposed package label well enough to use the drug safely and effectively on their own.”<sup>49</sup> In addition, Teva provided the results of a second study of 300 girls between the ages of eleven and sixteen showing that “they could use the product properly and safely.”<sup>50</sup>

The actual use data and labeling data, provided at the express request of the FDA after extended consultation with Teva,<sup>51</sup> satisfied the Center for Drug Evaluation and Research’s

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<sup>45</sup> *Id.* at 524, 549.

<sup>46</sup> Press Release, FDA, FDA Approves Over-the-Counter Access for Plan B for Women 18 and Older: Prescription Remains Required for Those 17 and Under (Aug. 24, 2006) (available at <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01436.html>).

<sup>47</sup> NDA approval letter from Scott Monroe, Supervisory Medical Officer, FDA, to Michele G. Walsh, Dir., Clinical Regulatory Affairs, Duramed Pharmaceuticals Inc., (July 10, 2009) (available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2009/021998s000ltr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/021998s000ltr.pdf)).

<sup>48</sup> Letter from Janet Woodcock, Dir. of CDER, to Bonnie Scott Jones, Esq., Center for Reproductive Rights (Docket 2001P-0075/CP1) (Dec. 12, 2011), available at <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM283545.pdf> [hereinafter Response to Citizen Petition].

<sup>49</sup> Stein, *supra* note 4, at A12.

<sup>50</sup> *Id.*

<sup>51</sup> Response to Citizen Petition, *supra* note 41, at 8.

(“CDER”) Office of New Drugs. An Associate Director of CDER stated in a memorandum dated October 4, 2011 that:

This product is already approved as a prescription product, and thus the safety and efficacy in the pediatric population have been established. Additional data were needed to support that the benefits and risks would be the same if the product was available OTC without a learned intermediary. . . . The studies provide data to demonstrate that women of child bearing potential of all ages can appropriately self-diagnose and administer Plan B One-Step in an OTC setting. . . . The safety and efficacy of OTC Plan B One-Step in this application is supported by the totality of the data submitted to support the application.<sup>52</sup>

After considering Teva’s supplemental NDA and the study data provided, FDA Commissioner Hamburg, on December 7, 2011, announced that she agreed with CDER’s findings that Plan B was “safe and effective in adolescent females, that adolescent females understood the product was not for routine use, that the product would not protect them against sexually transmitted diseases [, and that] . . . adolescent females could use Plan B One-Step properly without the intervention of a healthcare provider.”<sup>53</sup> The Commissioner therefore concluded that “there is adequate and reasonable, well-supported, and science-based evidence that Plan B One-Step is safe and effective and should be approved for nonprescription use for all females of child-bearing potential.”<sup>54</sup> In other words, the FDA had decided to approve Teva’s application and to grant unrestricted, OTC status to Plan B.

And yet, despite the Commissioner’s findings and the conclusions of CDER, the FDA did not approve Teva’s request for a complete prescription-to-OTC switch for Plan B. By way of explanation, Commissioner Hamburg stated that HHS Secretary Sebelius disagreed with the FDA’s determination and had invoked her authority under the Food, Drug, and Cosmetic Act to

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<sup>52</sup> *Id.* at 9.

<sup>53</sup> Hamburg Statement, *supra* note 9.

<sup>54</sup> *Id.*

instruct Hamburg to deny the application for nonprescription use of Plan B in females under the age of seventeen.<sup>55</sup> In a statement released on December 7, 2011, Sebelius explained:

[T]he switch from prescription to over the counter for this product requires that we have enough evidence to show that those who use this medicine can understand the label and use the product appropriately. I do not believe that Teva's application met that standard. The label comprehension and actual use studies did not contain data for all ages for which this product would be available for use. . . . The Secretary of the Department of Health and Human Services is responsible, acting through the FDA Commissioner, for executing the Federal Food, Drug, and Cosmetic Act. . . . I have directed the FDA to issue a complete response letter denying the supplemental new drug application (SNDA) by Teva Women's Health, Inc.<sup>56</sup>

Effectively, Sebelius argued that Teva's studies were inadequate to support unrestricted OTC availability for females of all ages because the studies failed to include sufficient data on usage and label comprehension by eleven-year-old females, ten percent of whom are capable of reproduction.<sup>57</sup>

President Obama, while denying any direct involvement in Sebelius's decision, said he supported her call on Plan B.<sup>58</sup> At a news conference, Obama cited parental concerns and "common sense," saying:

As the father of two daughters, I think it is important for us to make sure that we apply some common sense to various rules when it comes to over-the-counter medicine. . . . And as I understand it, the reason Kathleen made this decision was she could not be confident that a ten-year-old or an eleven-year-old, going to a drug store, should be able to, alongside bubble gum or batteries [purchase Plan B].<sup>59</sup>

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<sup>55</sup> *Id.*; see also Letter from Kathleen Sebelius, Secretary, U.S. Dept. of Health & Human Services, to Margaret Hamburg, Commissioner, FDA (Dec. 7, 2011), available at <http://www.hhs.gov/news/press/2011pres/12/20111207a.pdf> ("The Federal Food, Drug, and Cosmetic Act provides that 'the Secretary [of Health and Human Services], through the Commissioner, shall be responsible for executing' its provisions.") (citing 21 U.S.C. §393(d)(2)).

<sup>56</sup> Statement by U.S. Department of Health and Human Services Secretary Kathleen Sebelius, Dept. of Health & Human Services, (Dec. 7, 2011), available at <http://www.hhs.gov/news/press/2011pres/12/20111207a.html>.

<sup>57</sup> See *id.*

<sup>58</sup> David Jackson & Kelly Kennedy, *Plan B Decision Gets Obama's OK*, USA TODAY, Dec. 9, 2011 at 6A.

<sup>59</sup> *Id.*

Of course, whether an eleven-year-old *should* be able to purchase Plan B is a different question from whether eleven-year-olds are capable of understanding the instructions and using Plan B safely. Others expressing approval of Sebelius cited similar behavioral and social concerns, worrying that OTC availability of Plan B might have facilitated sexual abuse of young girls by allowing sexual predators to hide the evidence of assault, that it might have encouraged unprotected intercourse among minors, that it might have decreased parental control over children's behavior, and that it might have resulted in increased rates of sexually transmitted infections.<sup>60</sup>

Not everyone was persuaded by Sebelius's reasoning, however, and critics have suggested that her concerns about a lack of data regarding eleven-year-olds served to mask her real concerns about sexual activity among minors and the perception of Plan B as an abortifacient. Susan Wood, the FDA's Assistant Commissioner for Women's Health from 2000 to 2005, spoke out publicly against the decision, arguing that:

A review of the data shows that the availability of emergency contraception does not promote earlier or riskier sexual activity, but rather can prevent an unintended pregnancy if a woman - or adolescent - needs it. . . . [Sebelius's] fig-leaf explanation that there was inadequate data on young teens just doesn't hold water, and it is the same false rationale used years ago by those who blocked Plan B in the first place. . . . Her precedent-setting action undermines the principles of scientific integrity and science-based policymaking - and could pave the way for a future HHS secretary to overrule the FDA in other areas.<sup>61</sup>

Even assuming that Sebelius's decision was in fact based upon the scarcity of data regarding eleven-year-old users of Plan B and not on political or moral reservations, some critics have challenged the importance of the missing data. The Guttmacher Institute, for example, has deemed Sebelius's scientific argument "specious," explaining that although Sebelius was correct in observing that ten percent of eleven-year-old girls are capable of reproduction, the statistic

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<sup>60</sup> See Rob Stein, *Wider Access To Plan B Is Rejected*, WASH. POST, Dec. 8, 2011 at A01.

<sup>61</sup> Susan F. Wood, *On Plan B, A Broken Promise*, WASH. POST, Dec. 11, 2011 at B02.

misses the mark; in truth, “fewer than one percent of eleven-year-old girls are sexually active, but almost half of girls have had sex by their seventeenth birthdays, and most of these begin at age fifteen or sixteen.”<sup>62</sup> Effectively, the Guttmacher Institute suggests that unsupported concerns about the behavior of less than one percent of eleven-year-olds ought not prevent the sale of much-needed emergency contraception to the roughly fifty percent of females who have been sexually active by the age of seventeen.

Regardless of the motivation for Sebelius’s decision, there is no doubt that it will have a real effect on adolescent girls seeking to obtain emergency contraception. As detailed above, time is a critical factor when it comes to taking emergency contraception, and the requirement that a person schedule a doctor’s appointment, go to the office, meet with and pay the doctor, obtain a prescription, travel to a pharmacy and fill the prescription necessarily delays the person’s access to Plan B and thus is likely to decrease the pill’s effectiveness. Add in the challenges of finding a pharmacy with Plan B in stock, a pharmacist willing to dispense the drug, and approximately fifty dollars for the drug, and the task becomes even more onerous for the teenager seeking to take Plan B.

A recent study suggests that the existing prescription-OTC age divide routinely results in an improper denial of Plan B to seventeen-year-olds who are lawfully able to purchase Plan B without a prescription. A survey of 943 pharmacies found that twenty percent of pharmacies claimed not to have Plan B when asked, and of those pharmacies with the drug in stock, roughly twenty percent told callers posing as seventeen-year-old girls that they could not obtain Plan B

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<sup>62</sup> *HHS Secretary Kathleen Sebelius Overrides FDA Decision to Make Emergency Contraception More Broadly Accessible*, Guttmacher Institute, (Dec. 8, 2011), <http://www.guttmacher.org/media/inthenews/2011/12/08/> [hereinafter Guttmacher].



because of their age.<sup>63</sup> The misinformation was even more pronounced in low-income neighborhoods, where twenty-four percent of pharmacies said seventeen-year-olds could not obtain Plan B without a prescription.<sup>64</sup> With roughly a quarter of pharmacies in some areas denying seventeen-year-olds Plan B as recently as April of 2012, there is every indication that a switch to unrestricted OTC availability could have a major impact on the use of Plan B by young women.

The practical significance of Plan B's OTC availability comes even more sharply into focus when one considers the pervasive nature and the serious consequences of unplanned, teenage pregnancies in the United States. Each year, approximately 750,000 females in the United States between the ages of fifteen and nineteen become pregnant, with one-third of those pregnancies affecting females seventeen and younger, and with black and Hispanic females disproportionately affected by teenage pregnancy.<sup>65</sup> In addition to the direct physical and psychological impacts of teenage pregnancy on the mother, "more than two-thirds of those teenagers who decide to have their baby will not graduate from high school,"<sup>66</sup> and the cost of teenage pregnancies to the government run around seven billion dollars annually.<sup>67</sup> This is not to suggest that Plan B is a cure-all that would instantly solve the country's teen pregnancy

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<sup>63</sup> Tracey A. Wilkinson et al., *Pharmacy Communication to Adolescents and Their Physicians Regarding Access to Emergency Contraception*, 129 PEDIATRICS No. 4, 624 (April 2012).

<sup>64</sup> *Id.*; see also Maia Szalavitz, *Plan B: 1 in 5 Pharmacists May Deny Eligible Teens Access to Emergency Contraception*, TIME, March 26, 2012, available at <http://healthland.time.com/2012/03/26/plan-b-1-in-5-pharmacists-may-deny-eligible-teens-access-to-emergency-contraception/>.

<sup>65</sup> See Kathryn Kost, Stanley Henshaw & Liz Carlin, *U.S. Teenage Pregnancies, Births and Abortions: National and State Trends and Trends by Race and Ethnicity*, GUTTMACHER INSTITUTE (Jan. 26, 2010), available at <http://www.guttmacher.org/pubs/USTPTrends.pdf>; see also Sydney Kokjohn, *The Imposition of an Age Restriction on Over-the-Counter Access to Plan B Emergency Contraception: Violating Constitutional Rights to Privacy and Exceeding Statutory Authority*, 9 MINN. J. L. SCI. & TECH. 369, 383 (2008).

<sup>66</sup> Vanessa Lu, *The Plan B Age Restriction Violates A Minor's Right To Access Contraceptives*, 44 FAM. L.Q. 391, 391 (2010).

<sup>67</sup> *Id.*

problem,<sup>68</sup> but without doubt, access to and education about contraception – including emergency contraception – is an issue of vital importance to adolescent female health as well as to the economic wellbeing of these women and the nation.

### **III. Executive Influence: Analyzing the Relationship Between HHS and the FDA**

#### *A. Delegation and the OTC Switch: Understanding The Legal Relationship between HHS and FDA*

Under the Food, Drug, and Cosmetic Act of 1938<sup>69</sup> (“FDCA”) and subsequently enacted amendments, the prescription to OTC switch can be achieved in a few ways. As was the case for Plan B, the manufacturing company can file a supplemental NDA with the FDA’s Division of Nonprescription Clinical Evaluation (“DNCE”), seeking approval for the switch.<sup>70</sup> The OTC review process is then overseen by DNCE – a component of CDER.<sup>71</sup> According to the 1951 Durham-Humphrey Amendment to the FDCA, OTC drugs are defined as those drugs that do not require medically supervised use for safety and have not been approved for use under NDAs mandating medical supervision.<sup>72</sup>

More recently, the 1962 Kefauver-Harris Amendments imposed the requirement of effectiveness and introduced the practice of balancing a drug’s benefits against its risks when making prescription-to-OTC switch decisions.<sup>73</sup> Accordingly, the FDA reviewing panel now considers the ability of consumers to self-diagnose the relevant condition addressed by the drug

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<sup>68</sup> Gardiner Harris, *Agency Agrees to Ease Access to Emergency Contraceptive for 17-Year-Olds*, N.Y. TIMES, Apr. 23, 2009, at A14 (quoting the Director of the Office of Population Research at Princeton University who suggests that access to Plan B will not solve the teen pregnancy crisis).

<sup>69</sup> The Act as passed in 1938 actually made no distinction between prescription and OTC drugs prior to the 1951 Durham-Humphrey Amendment.

<sup>70</sup> See 21 U.S.C. § 310.200(b) (2004).

<sup>71</sup> *Frequently Asked Questions on the Regulatory Process of Over-the-Counter (OTC) Drugs*, FDA (April 16, 2012) <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069917.html>.

<sup>72</sup> See 21 U.S.C. § 353(b)(1)(A) (2004).

<sup>73</sup> 21 C.F.R. § 330.10(a)(4) (a drug’s risk-benefit ratio must be considered by the reviewing panel when it evaluates the drug’s safety and effectiveness).

and to understand and follow the label instructions.<sup>74</sup> In addition, the panel makes an assessment of the drug's effectiveness and safety when subjected to OTC use. "While not bound by the advisory committee's counsel, the FDA almost always follows its recommendation."<sup>75</sup> More specifically, the FDA followed the Advisory Committee's recommendation "in every OTC switch decision between 1994 and 2004."<sup>76</sup> Another path to OTC status allows an interested party like the Center for Reproductive Rights to petition the FDA to make the switch,<sup>77</sup> and in certain cases, companies can pursue OTC status via the monograph route.

The FDCA, which Sebelius cited in her December 7 decision on Plan B, vests in the Secretary of HHS the authority to free a drug from the restrictions of prescription status "when such requirements are not necessary for the protection of the public health."<sup>78</sup> This provision is representative of the majority of the FDCA, which by its plain language serves almost exclusively as a means of granting authority to "the Secretary." However, much of the Secretary's authority under the FDCA has since been explicitly and formally delegated to the FDA Commissioner and others.<sup>79</sup> 21 C.F.R. § 310.200(B) provides that:

Any drug limited to prescription use under section 503(b)(1)(B) of the act shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and he finds that the drug is safe and effective for use in self-medication as directed in proposed labeling.<sup>80</sup>

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<sup>74</sup> *Regulation of Nonprescription Products*, FDA (Jan. 26, 2010) available at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm093452.html>; see also Samantha Harper, "The Morning After: How Far Can States Go to Restrict Access to Emergency Contraception?", 38 COLUM. HUM. RTS. L. REV. 221, 228 (Fall 2006).

<sup>75</sup> *Now Available Without a Prescription*, FDA (Aug. 12, 2011), available at <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143547.htm>.

<sup>76</sup> Percival, *supra* note 42 at 2522 (citing Tummino, 603 F. Supp. 2d at 528).

<sup>77</sup> *Now Available Without a Prescription*, *supra* note 75.

<sup>78</sup> 21 U.S.C. § 353(b)(3) (2004).

<sup>79</sup> Tummino, 603 F. Supp. 2d at 524 (citing 21 U.S.C. § 393(d) (2006)).

<sup>80</sup> 21 C.F.R. § 310.200(B) (2007).

More explicitly, the FDA Staff Manual Guidelines clearly state that the Secretary has redelegated to the Commissioner all “functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act,” though the Secretary reserves the authority “to approve regulations of the FDA.”<sup>81</sup> Thus, while the Commissioner of the FDA has assumed the Secretary’s authority to determine that protection of the public health does not require prescription status for a given drug, the Secretary of HHS has retained her authority to approve any regulation that the Commissioner seeks to pass while acting in furtherance of the authority delegated to her. As will be explored below, the extent to which a given Secretary utilizes her reviewing authority varies greatly over time.

#### *B. HHS and the FDA Over the Years: A History of Behind-the-Scenes Influence*

By definition, behind-the-scenes influences and pressures are removed from the public eye. As a result, direct evidence of HHS or other executive branch influence on FDA decisions is scarce and largely anecdotal. The December 7, 2011 decision regarding Plan B, therefore, is unique in its very public nature. But is such an exertion of authority by HHS really that unusual? Discovery in the *Tummino* case, for example, revealed evidence of politically-charged conversations regarding an earlier Plan B OTC switch and suggested that pressure from the White House played a large role in the FDA’s decision.<sup>82</sup> To understand the significance of HHS’s influence over the FDA’s decisions regarding Plan B, it is vital to look back in time and to place the 2011 decision in historical context. A careful study of the statements of former FDA administrators from the past fifty years reveals that Plan B is not the first product over which the

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<sup>81</sup> FDA Staff Manual Guides, Vol. II, § 1410.10, FDA, May 18, 2005 (available at <http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm080711.htm>).

<sup>82</sup> See Percival, *supra* note 42, at 2521-2524.

FDA and HHS have disagreed, nor was December 7, 2011 the first instance in which the Secretary of HHS has overruled an FDA decision.

According to retired FDA administrator Arthur Checchi, who worked for the FDA from 1945 through 1959, the FDA initially operated as a small, low-budget, professional organization subject to little attention from the Secretary<sup>83</sup> or the White House during much of its early history.<sup>84</sup> Not until the Citizens' Advisory Committee in 1955 and 1956 did the FDA start receiving increased Congressional, public and political interest, and relatedly, increased funding.<sup>85</sup> As the FDA began to receive larger annual appropriations, growing from an organization of hundreds to one of thousands of workers, it naturally began to have a greater national impact and thus to attract more attention from the newly interested executive and legislative branches.

Checchi recalled one of the earliest instances of a Secretary's direct involvement with FDA affairs dating back to 1959 and the issue of cranberries contaminated with aminotriazole.<sup>86</sup> "For the first time in the history of the Food and Drug Administration . . . the political master, if you will, had made an FDA decision. It was the Secretary's Department, I believe that made that decision on the aminotriazole."<sup>87</sup> Wallace Janssen, former Director of the Office of Public Information, recalled that the FDA had informed then-Secretary Arthur Flemming about the

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<sup>83</sup> Although some early Secretaries might have paid less attention to the FDA, that is not to suggest that FDA Commissioners shied away from approaching the Secretary when action was needed. Then-acting Secretary of Agriculture Rexford Guy Tugwell recalled one instance in 1933 when he was approached by the FDA Commissioner regarding the use of lead arsenate as an apple insecticide. Tugwell agreed to regulate the pesticide and faced intense criticism for the decision from apple-growers and their congressional representatives as well as from the newly-instated Secretary of Agriculture who felt the Department should protect farmers and not consumers. See Interview by Charles Jackson with Rexford Guy Tugwell, Assistant Secretary of Agriculture, in Santa Barbara, Cal. (June 7, 1968) at 2-6, available at <http://www.fda.gov/AboutFDA/WhatWeDo/History/OralHistories/SelectedOralHistoryTranscripts/default.htm>.

<sup>84</sup> Interview by James Harvey Young with Arthur Checchi, FDA administrator, Rockville, Md. (June 30, 1978), at 20-21 ("Now, you raise the question of attention from the White House attention from the Secretary's office. Substantially, we got none") [hereinafter Checchi].

<sup>85</sup> *Id.* at 21-23.

<sup>86</sup> *Id.*

<sup>87</sup> *Id.* at 23.

finding of aminotriazole in cranberry shipments because Flemming “wanted to be informed about all of the important developments . . . and then very often he would personally take charge.”<sup>88</sup> Checchi was unsure as to whether the Secretary directly overruled the FDA commissioner regarding aminotriazole, but he was certain that “the Secretary of the Health, Education and Welfare gave the Commissioner a direct order as to what to do.”<sup>89</sup>

Interestingly, the aminotriazole decision sparked similar concerns to the Plan B decision regarding the potential loss of FDA independence. Janssen, when asked for his thoughts on the subject, argued that it was inaccurate to characterize the Secretary’s action on aminotriazole as a sign that the FDA had suddenly lost its independence, saying that the action was in fact largely consistent with the FDA’s history:

For instance, when Oscar Ewing was head of the Federal Security Agency<sup>90</sup> . . . he very much occupied himself with Food and Drug matters, to the extent that regulations piled up on his desk and laid there for months because he didn't have time to get around to read all of them and sign them out. He insisted on doing all that. So, Flemming was certainly not the first of the Secretaries to get involved with the FDA's affairs. Further back, Secretary of Agriculture James Wilson<sup>91</sup> was another who involved himself. It varies with the Secretary as to how much they involved themselves with the affairs of the FDA.<sup>92</sup>

According to Janssen, Flemming insisted that the FDA keep him fully informed about important agency action via weekly reports, but reasoned that “being the responsible head of the department and the chief spokesman of the department, [the Secretary] had a right to know what was going on.”<sup>93</sup>

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<sup>88</sup> Interview by James Harvey Young with Wallace F. Janssen, Director of the Office of Public Information, FDA, Rockville, Md. (Jan. 30-31, 1984) at 97 [hereinafter Janssen].

<sup>89</sup> Checchi, *supra* note 84, at 24.

<sup>90</sup> Oscar Ewing was the head of the Federal Security Agency from 1947 to 1953. The Federal Security Agency was abolished in 1953, and most of its responsibilities and functions were transferred to HEW.

<sup>91</sup> James Wilson served as the Secretary of Agriculture from 1897 to 1913.

<sup>92</sup> Janssen, *supra* note 88, at 99.

<sup>93</sup> *Id.* at 100.

Former General Counsel to the FDA William Goodrich also recalled speaking with Flemming after an aminotriazole-related seizure, when the Secretary wondered why he had not been informed about the issue earlier and asked about the possibility of requiring the Secretary's approval of all FDA regulations.<sup>94</sup> According to Goodrich, he had been able to obtain authority for the FDA to issue regulations "without having to go through the Secretary's office . . . from either Folsom or maybe as far back as Ewing," primarily as a result of Ewing's frustration with being required to review countless complex antibiotic regulation papers.<sup>95</sup> When Flemming pushed for more oversight authority, Goodrich argued against it:

I said, "You don't want to do that. It just invites a political intervention in things that are not political, and it doesn't assure you anything you can't get through proper management of these people that are employees of the Secretary and that won't respond. I know from having worked here a long time and knowing the people, if you tell them to do certain things, they're going to do it. And you can rely just as well on that." <sup>96</sup>

Despite his best efforts, Goodrich ultimately witnessed what he described as the "taking away from Food and Drug the authority I got for them a long, long time ago to issue regulations without having to go through the Secretary's office."<sup>97</sup>

By the mid-1960's, the Secretary's position of authority in relation to sensitive FDA decisions was well established but strongly tied in practice to the preferences of the Secretary in power at the time. FDA Commissioner James Goddard, who served from 1966 to 1968, recalled

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<sup>94</sup> Interview by Ronald T. Ottes with William W. Goodrich, General Counsel, FDA, Rockville, Md. (Oct. 15, 1986), at 124-25.

<sup>95</sup> Goodrich told Ewing to "put out a directive to them, and say, 'I've given you this authority. I want to be damn sure that anything that involves any policy thing is explained and alerted to me. *Id.* at 124 ("it took Ewing days. He was a lawyer, and he sat down with that thing and didn't do anything else for two or three days. So when he got through, he was inclined to go along. So I got them to put that regulation in that said Food and Drug would have the authority").

<sup>96</sup> *Id.* at 125.

<sup>97</sup> Goodrich points to the efforts of C.C. Johnson, the former head of the short-lived Consumer Protection and Environmental Health Services office, to exert review authority as the start of the erosion of the FDA's ability to pass regulations without approval by the Secretary. *Id.* at 124. In a similar vein, former FDA Commissioner Herbert Lay complained that CPEHS frequently demanded that the FDA explain why it wanted the Secretary to take action in a manner that "became a real impediment." Interview by Ronald T. Ottes with Herbert L. Ley, FDA Commissioner, Rockville, Md. (Dec. 15, 1999), at 9 [hereinafter Ley].

several occasions where he had approached Secretary of Health, Education, and Welfare<sup>98</sup> (“HEW”) John Gardner with politically sensitive issues regarding the regulation of dietary products, vitamin claims, and more:

[I] informed him of what was about to happen. At the same time, gave him an opportunity to overrule me if he so chose, but that wasn't why I went there, and I said, "Mr. Secretary, I bring this issue to you not because I haven't been able to make a decision, but because I've made a decision. I want you to be aware of the implications of that decision. And, of course, if you wish to change that and recommend that I take another course, that's another matter. . . ."<sup>99</sup>

Although Goddard admits to briefing the Secretary on sensitive decisions and seeking his approval, he said that Secretary Gardner consistently backed his decisions as Commissioner “without exception.”<sup>100</sup> In one particular instance, Goddard recalled making a sensitive decision regarding the sale of processed whole fish without asking for the Commissioner’s consent, though he noted that he would have respected the Secretary’s position had he come to him and objected.<sup>101</sup>

The relationship between the Commissioner and Secretary changed, however, when Wilbur Cohen replaced Gardner as Secretary of HEW. According to Goddard, Cohen was an overly authoritative Secretary who “dealt in political expediencies,” and the clash between the two was the primary reason Goddard decided to leave the FDA in 1968:

The thing that really made me decide to get out fast was I found that Wilbur had committed the Food and Drug Administration to position on an issue with a senator without consulting me ahead of time, and that was when I decided that if politics were going to have that much to say, I couldn't stay on. . . . I ran the Food and Drug Administration. And then all of sudden, Wilbur made a decision and then advised me he had made that. Now, that was his prerogative, I understand

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<sup>98</sup> The Department of Health, Education, and Welfare was renamed the Department of Health and Human Services in 1979.

<sup>99</sup> Interview by James Harvey Young with James L. Goddard, FDA Commissioner, Atlanta, GA (April 30 to June 19, 1969) at 152, 351-54.

<sup>100</sup> *Id.* at 354.

<sup>101</sup> *Id.* at 368-70 (the approval of whole fish processed into paste or meal had attracted significant congressional attention because of the view that the product could be a useful protein source in developing countries and because Congress believed the FDA had been stalling the decision-making process).



that, but it's poor leadership in that situation, as it was a technical issue. It happened to be a technical thing, and he wasn't competent to make that kind of judgment. It was made for political reasons only, and solely on the basis of political expediency.<sup>102</sup>

Although Goddard did not identify the particular decision in question, his complaint – namely that the Secretary committed the FDA to a decision on a scientific issue solely for political reasons – mirrors much of the criticism leveled at Sebelius's decision made more than forty years later.

According to former FDA Commissioner Herbert Lay, by the late 1960's, the FDA was dealing with yet another significantly involved Secretary in the form of Robert Finch. Finch adopted a five-day policy which stated that the “FDA had to notify the Secretary five days in advance of any drug or product action which was anticipated to cause a public concern.”<sup>103</sup> Finch's assertion of review authority caused significant tension between HEW and the FDA in April of 1969, when Lay sent Finch a memorandum notifying him of the FDA's decision to remove the ineffective and inappropriately marketed combination antibiotic Panalba from the market.<sup>104</sup> To Lay's surprise and displeasure, the Secretary's office “suggested” a different course of action on Panalba.<sup>105</sup> Lay also remembered being summoned to the Secretary's office in 1969 to present possible courses of action regarding the artificial sweetener cyclamate only to have the Secretary make the decision.<sup>106</sup> Lay is “absolutely positive that I was ordered not to discuss what happened in the Secretary's Office or any proposed action [regarding cyclamate]

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<sup>102</sup> *Id.* at 407-09.

<sup>103</sup> Ley, *supra* note 97, at 10.

<sup>104</sup> PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION 175 (UNC Press) (2003); *see also* Ley, *supra* note 97, at 18-19 (“We proposed to decertify the product and to decertify albamycin as a separate product, for which the Academy could not find good reason for efficacy. At this point, it really became a political issue. . . it was also clear that Upjohn was lobbying the Secretary in terms of meetings between Upjohn and the Secretary and that Upjohn had made all sorts of proposals to delay the decertification while they got more data.”)

<sup>105</sup> *Id.*

<sup>106</sup> Ley, *supra* note 97 at 21-22.

with a single FDA member.” Fortunately, Ley was able to speak freely after retiring from the FDA, allowing his experience with HHS’s behind-the-scenes influence of FDA decisions to finally come to light.

By way of explanation for the shift from little political attention to active political involvement, Checchi points to a shift over time from career Commissioners<sup>107</sup> to politically-oriented Commissioners, which he believes resulted in the creation of an FDA that is “really responsive to the political party in power.”<sup>108</sup> Checchi’s observations were echoed by Daniel Banes, the Director of the Office of Pharmaceutical Sciences who worked for the FDA from 1939 to 1973.<sup>109</sup> Banes similarly noted a shift over time away from career Commissioners as the FDA grew, but he believed it was inaccurate to say that Commissioners of the past were free of political influences:

I think there have been political pressures throughout the history of the [FDA]. The question is how have they been met. . . . Before the arrival of Commissioner Goddard, the FDA high brass was promoted through the ranks. And there was less of a feeling that political attachments were involved. . . . In the time of appointments from within, the feeling was that the Commissioner remains at the helm no matter what kind of administration. He holds the power whether a Republican or Democratic administration - the Commissioner remained unchanged. But since Goddard’s time, the Commissioner has been expected to turn in his resignation when administrations change. Consequently, there seems to be a political connection between the head of the [FDA] and the Chief Executive. And, on that basis, it would seem that there is a political tinge to FDA activities.<sup>110</sup>

Checchi similarly acknowledged that even in the FDA’s early years, the views of the president’s administration were a guiding force for the agency because “you had to be damned sure you

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<sup>107</sup> George P. Larrick, FDA Commissioner from 1954 to 1965 observed that “the FDA from bottom to top is made up of civil servants.” Interview by Richard K. Hopkins of George P. Larrick, FDA Commissioner, Marathon Fl. (Jan 12 1968), at 25.

<sup>108</sup> Checchi, *supra* note 84, at 180.

<sup>109</sup> Interview by James Harvey Young with Daniel Banes, Director, Office of Pharmaceutical Sciences, FDA, Silver Spring, Md. (June 17, 1980), at 43-44.

<sup>110</sup> *Id.* at 44-45.

didn't offend the boys in the White House. As you were in the Commissioner's Office you were sensitive to the fact that the great white eminence sat there and you had to be careful.”<sup>111</sup>

Five years after Commissioner Goddard's departure, FDA Commissioner Alexander Schmidt made it a point to push back against outside influences on FDA decisions in 1973, actively resisting interference from the Secretary and the President:

One of the things I was concerned about when I went there, was that I'd be commissioner of Food and Drugs and I'd be able to run the agency. I talked to the people at the White House and I talked to Cap Weinberger and sort of made a deal. And that was that I would keep Cap and the White House informed of anything they needed to be or should be informed of so they wouldn't be surprised and they wouldn't get hit on the back of the head with a wet fish or whatever, and I would run the agency well. And in return for that, they would leave me alone. And that's the way we operated, and I was very firm in turning back any approach to the agency, either from downtown or, on one or two occasions from the White House or from the OMB, when they made a move that might "usurp" our prerogatives.<sup>112</sup>

Schmidt credited his ability to run the FDA generally free from political interference in part to the fact that he was a well-respected member of the political party in power, and in part to his willingness to stand up for the agency's independence, putting his job on the line when necessary.<sup>113</sup> Schmidt also worked with Secretaries who were either supportive of his work at the FDA, like Casper Weinberger, or disinterested, like David Matthews.<sup>114</sup> Since his departure from the FDA, however, Schmidt observed a decrease in the Commissioner's "authority to run the agency and make decisions. That has changed dramatically to this day.”<sup>115</sup>

FDA Commissioner Donald Kennedy, who served from 1977 to 1979, largely echoed Schmidt's sentiments, noting that Secretary Joe Califano "had an array of bright young lawyers

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<sup>111</sup> Checchi, *supra* note 84, at 182.

<sup>112</sup> Interview by James Harvey Young of Alexander M. Schmidt, FDA Commissioner, Chicago, Ill., (March 8-9, 1985) at 27.

<sup>113</sup> *See id.* at 28-29.

<sup>114</sup> *Id.* at 94.

<sup>115</sup> *Id.* at 27-31.

whom he instructed to kind of keep track of what was going on in the agency, and they would often cause us to need to do more explanation than I thought was necessary.”<sup>116</sup> While recognizing that the Secretary should be kept informed about the FDA’s politically sensitive work, Kennedy argued that “Joe probably could have given the agency a longer leash,” because the FDA “needs a certain amount of independence, I always felt. Something I was convinced of from the beginning was that it was important for FDA to have independent regulation writing authority.”<sup>117</sup>

Whether it is a product of true change over time or simply nostalgia, the belief that the Commissioner’s independence has been dampened with the passing of years or that politics have come to play a greater role in FDA decisions is a common one among former Commissioners. Frank Young, FDA Commissioner from 1984 through 1989, when asked whether he would change course on RU-486 based on differing political views, responded “absolutely not. . . . the day you make FDA’s approvals political instead of on safety and effectiveness, you have killed the public protection.”<sup>118</sup> When asked about the role of politics in the FDA more than ten years later, however, Young said he “lament[ed] what I would consider a much more politicizing of the agency.”<sup>119</sup>

Unfortunately, Young’s belief in a non-political FDA appears somewhat divorced from the historical record of agency action even prior to his reign as Commissioner in the 1980’s. In 1981, for example, the FDA decided to ban raw milk as a potentially adulterated food that carried a risk of salmonella poisoning:

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<sup>116</sup> Interview by Robert Tucker with Donald Kennedy, FDA Commissioner, San Francisco, Cal. (June 17, 1996), at 6-7.

<sup>117</sup> *Id.* at 7.

<sup>118</sup> Interview by Ronald T. Ottens with Frank Young, FDA Commissioner, Bethesda, Md. (Dec. 8, 2000), at 41-42.

<sup>119</sup> *Id.*

Doctors, scientists, and public health officials, including those inside HHS and the FDA, made it clear there was no case for raw milk. Alta Dena, however, was located in the district of Republican Representative Bill Dannemeyer, who . . . took his pleading to the White House and HHS Secretary Margaret Heckler, as well as to the FDA. . . . The FDA was ordered off the case. The assistant secretary of HHS who delivered the message, Dr. Robert Rubin, wrote that the HHS “nonconcur[red]” with the FDA ban. . . . Hayes made known his recommendation that raw milk be banned. But the Office of Management and Budget ordered the agency not to act, and it didn’t.<sup>120</sup>

In 1985, following similar delays in the regulation of nitrites and potentially carcinogenic cosmetic dyes, former Commissioner Schmidt famously told state regulators that “[w]e have more politicization of the agency than is either warranted by rational politics or good for the American people.”<sup>121</sup>

In one of the best-known instances of the executive branch overruling an FDA decision, the FDA, as a result of industry lobbying and OMB interference, “delayed for two years the decision to require Reye’s warnings on aspirin labels.”<sup>122</sup> Reye’s syndrome, a potentially fatal disease, was linked by the Centers for Disease Control to the use of aspirin by children in 1981, and the FDA then proposed requiring a warning label on aspirin bottles.<sup>123</sup> However, aspirin-makers vigilantly and successfully lobbied OMB, which in turn “rejected the work that it had taken scientists at the FDA more than six months to complete. Shortly thereafter, the FDA decided to kill the proposed regulation.”<sup>124</sup>

As a result, it was not until 1986 that the FDA finally issued a regulation requiring an aspirin warning label.<sup>125</sup> The delay undoubtedly cost children’s lives when one considers that 555 children died of Reye’s in 1980 but fewer than thirty-seven cases have been reported

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<sup>120</sup> HILTS, *supra* note 104, at 222.

<sup>121</sup> Michael L. Millenson, *Fda 'Politicization' Called Hazardous To Health*, CHICAGO TRIBUNE, Oct. 20, 1985, at 10C.

<sup>122</sup> Michael Specter, *New Freedom For the FDA Commissioner?*, WASH. POST, Feb. 9, 1988, at A21.

<sup>123</sup> William B. Schultz & David C. Vladeck, *An Obstacle to Public Safety*, WASH. POST, May 10, 1988, at Z20.

<sup>124</sup> *Id.*

<sup>125</sup> *Id.*

annually since 1987.<sup>126</sup> Accordingly, the aspirin case serves as an important reminder that the FDA serves a critical function in protecting public health, and that interference with FDA functions can have devastating real world consequences. Unfortunately, this lesson seems quickly forgotten. As recently as December 2008, the FDA acknowledged that political pressure from Congress and other sources prompted the Commissioner to improperly approve Menaflex, a patch device for knee repair, as substantially equivalent to grandfathered devices despite FDA reviewers' conclusions that it was not equivalent and that more studies of the device's safety and efficacy were needed.<sup>127</sup>

## **Conclusion**

After reviewing more than fifty years of HHS-FDA relations, it becomes immediately apparent that a Secretary's decision to override an FDA determination is, if not commonplace, at least not unprecedented. As described above, there have been ebbs and flows of HHS interference with the FDA coinciding with the changing of individual Secretaries and Commissioners, and perhaps there has been a shift towards a more politically-oriented FDA given the demise of the career Commissioners. But to say that Plan B represented the first instance in which the Secretary of HHS overruled the FDA Commissioner is to forget the lessons of Secretary Flemming and aminotriazole, of Commissioner Goddard and Secretary Cohen, of Secretary Finch and Panalba, Secretary Heckler and raw milk, and OMB and aspirin.

What separates the interference of the past and the interference of the present is the very public nature of Sebelius's overruling of the FDA regarding the Plan B prescription-to-OTC

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<sup>126</sup> Catherine O'Neill Grace, *The Fall of Reye's*, WASH. POST, May 18, 1999, at Z22.

<sup>127</sup> See Gardiner Harris & David M. Halbfinger, *F.D.A. Reveals It Fell to a Push By Lawmakers*, N.Y. TIMES, Sept. 25, 2009, at A1; Gardiner Harris, *F.D.A. Vows to Revoke Approval of Device*, N.Y. TIMES, Oct. 15, 2010, at A22.

switch. Those who worry that the December 7 decision could signal the erosion of FDA authority and the beginning of frequent overruling of the FDA,<sup>128</sup> would do well to look to history and to witness the Secretary's use of precisely this authority in the past to influence FDA decisions behind closed doors. Whatever one may think of HHS intervention in FDA affairs, it is certainly not an unprecedented occurrence of great historical significance.

Regardless of its historical import, Sebelius's choice to take a nontraditional, public approach to her Plan B decision is ripe for analysis; perhaps the decision was agreed upon in advance and Sebelius merely sought to protect the FDA Commissioner from the internal agency backlash that would have followed had the Commissioner herself rejected Teva's supplemental NDA. Under this theory, the overruling allowed Hamburg to retain the respect and loyalty of the FDA's science-minded employees. It is also possible, though perhaps less likely, that HHS and the FDA truly did square off on Plan B and that the Secretary pulled rank.

No matter the reason for Sebelius's public announcement, her tactic has the potential to increase transparency in agency decision making. Rather than allowing politics to dictate scientific decisions behind closed doors, a public disagreement may help to segregate the scientific mission of the FDA from the political interests of the Secretary of HHS. Forcing the Secretary to publicly accept responsibility for her decision has the benefit of increasing democratic accountability as well. Of course, in order to truly maximize transparency, the Secretary would have to openly admit that political or social considerations governed her decision rather than use a scientific rationale to mask her reasoning whenever such considerations were determinative.<sup>129</sup> As an added benefit, this course of action would be

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<sup>128</sup> See Wood, *supra* note 61, at B2.

<sup>129</sup> See, e.g., Nina A. Mendelson, *Disclosing "Political" Oversight Of Agency Decision Making*, 108 MICH. L. REV. 1127 (2010) ("Agencies should be required to summarize executive influence on significant rulemaking decisions. Such an ex ante disclosure regime is superior to proposals that judges be more receptive to political

consistent with President Obama's 2009 instruction to federal agencies that the preservation of scientific integrity in agency decision making is of the highest priority.<sup>130</sup>

As discussed above, there are some indications that social and political concerns about the effects of Plan B on the sexual activity of minors guided Sebelius's decision and not a concern about the underrepresentation of eleven-year-olds in usage studies, meaning that socio-political pressure overwhelmed the scientific record of Plan B's safety and efficacy.<sup>131</sup> If that was the case, *Tummino* suggests that litigation could eventually force the FDA to approve an unrestricted prescription-to-OTC switch for Plan B.<sup>132</sup> Given the speed of the courts, however, there could be a significant delay in obtaining that result, and assuming that Teva does not submit additional studies regarding eleven-year-old users of Plan B, it could be years before Plan B is available without restriction on drug store shelves if it ever obtains complete OTC status.

Meanwhile, likely due to the Secretary of HHS's consideration of political and social factors disguised as scientific concerns, sexually active low income and minority female adolescents in the United States will disproportionately bear the burdens of restricted access to time-sensitive emergency contraception. That fact alone should have made the December 7, 2011 decision to overrule the FDA on the prescription-to-OTC switch of Plan B a decision of

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reasons in reviewing a particular agency action. . . . [W]hile some, but not all, political reasons for agency action are legitimate, only a more transparent system--one that facilitates public dialogue and accountability to Congress--can fully resolve the question of which reasons are legitimate and which are not."); *see also* Gregory W. Reilly, *The FDA and Plan B: The Legislative History of the Durham-Humphrey Amendments and the Consideration of Social Harms in the Rx-OTC Switch* (2006), in *FOOD AND DRUG LAW: AN ELECTRONIC BOOK OF STUDENT PAPERS* (Peter Barton Hutt, ed.) (arguing that "social harms are appropriate considerations for the Rx-OTC decision if they are true societal costs of a drug, specifically, if they are quantifiable, generally accepted, and a reasonable probability," but that "by failing to acknowledge that it was considering social harms the FDA threatened the transparency necessary to administrative accountability.")

<sup>130</sup> *See* Memorandum from Barack Obama, President of the U.S., for the Heads of Executive Dep'ts & Agencies (Mar. 9, 2009), available at [http:// www.whitehouse.gov/the\\_press\\_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/](http://www.whitehouse.gov/the_press_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/).

<sup>131</sup> *See* Guttmacher, *supra* note 62.

<sup>132</sup> *See* *Tummino v. Torti*, 603 F. Supp. 2d 519 (E.D.N.Y. 2009).



national interest, regardless of whether it represented the first or thousandth time that the Secretary of HHS overruled the FDA.